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MEDIA MENTION

Wiley Rein Attorneys Discuss Proposed Law to Limit Regulation of Health IT

eHealth Law & Policy
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Wiley Rein attorneys Sonali P. Gunawardhana and Scott D. Delacourt were quoted in an *eHealth Law & Policy* article published in the March 2014 issue on a proposed law to limit the regulation of health information technology (IT).

The bill, proposed by U.S. Sens. Deb Fischer (R-NE) and Angus King (I-ME), would carve out exceptions in the Federal Food, Drug, and Cosmetic Act—which gives the Food and Drug Administration (FDA) authority to oversee the safety of medical devices including oversight over segments of health information technology which encompasses a wide range of products and services—including software, hardware and infrastructure—designed to collect, store and exchange patient data throughout the clinical practice of medicine . Critics have said that limiting FDA oversight could put patient safety at risk. Others have suggested a more moderate approach, one that balances regulatory certainty with patient safety.

"It would be beneficial if we could come up with a more refined approach that distinguishes high-risk health IT products (including mHealth apps) from low-risk products, allowing the FDA to better define which types it will definitively regulate in the future," Ms. Gunawardhana and Mr. Delacourt said.

Ms. Gunawardhana, of counsel in Wiley Rein's Food & Drug Law Practice, worked for nearly 10 years as an attorney at the FDA, including serving in the Center for Devices and Radiological Health. Mr. Delacourt, a partner in the firm's Communications and Privacy practices, has a broad range of experience in wireless, telecom, mobile marketing, and data privacy issues.

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